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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,262	10/16/2003	Klaus Rudolf	1/1402	9943
28501 7590 02/27/2007 MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368			EXAMINER CHANG, CELIA C	
			ART UNIT 1625	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE 3 MONTHS			MAIL DATE 02/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/687,262	Applicant(s) RUDOLF ET AL.	
	Examiner Celia Chang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment and response filed by applicants dated Dec. 21, 2006 have been entered and considered carefully.

Claims 13-16 have been canceled. Claims 1-12 are pending.

2. The objection of claims 10-12 as being improper multiple dependent format is dropped in view of the amendments to the claims.

3. The rejection of claims 12 under 35 USC 101 for lacking method steps is dropped in view of the amendment to the claim.

4. The rejection of claims 1-11 under 35 USC 112 first paragraph for lacking enabling support for hydrates is maintained for reason of record.

Contrary to diastereomers or addition salt of a compound which can be obtained after the compound is made and in possession. Hydrates are separate chemical identities from a compound i.e. a different compound. Absent of any hydrate being made, the mere allegation of hydrates thereof lacks enablement since the specification provided no guidelines as to which one among the enormously mixed and matched Markush groups can form hydrates and under what condition can a hydrate instead of compound per se be made.

5. Claims 11-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The currently amended claim 12 is drawn to method of treating or reducing frequency of headache, migraine etc. or a host having an increased risk of suffering from headache or cluster headache etc. For which there is no antecedent basis in the specification. The only utility for the disclosed compound is implicitly disclosed on page 1 of the specification being a CGRP antagonist. No where in the specification any of the compound has been shown to have

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biological activity such as binding activity, IC50 etc. as provided description to dosage estimation for pharmaceutical formulation of claim 11 nor treating any physio-pathology as claimed in claim 12.

The term "host having an increased risk of suffering from a headache, migraine or cluster headache" is considered new matter since no antecedent basis for such condition.

Removal of all new matter is required.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

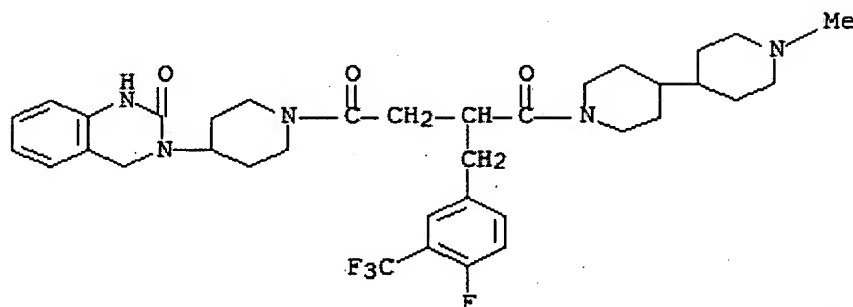
Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudolf et al.

US 6,344,449 supplemented with structural delineation of compounds by CA 128:257695.

Determination of the scope and content of the prior art (MPEP §2141.01)

Rudolf et al. '449 disclosed compounds active in treating pain (col. 85, lines 35-36) generically encompassed the instant claims. A structural analogous species has been delineated by CA 128:257698 as

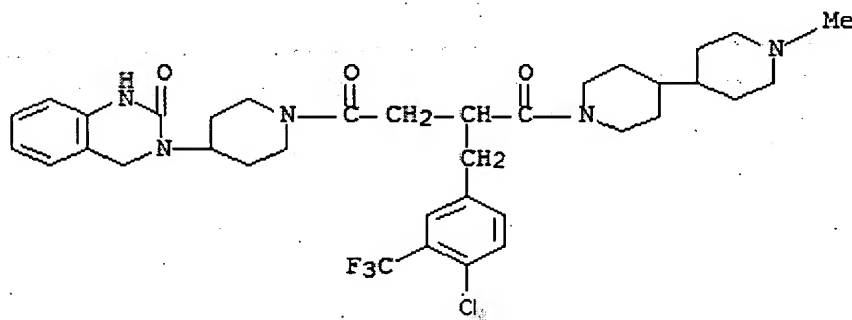
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see CA 128:257698 copy attached, compound marked on page 3.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the above species i.e. compare compound 184 of claim 9 with the above compound, is that instead of a 4-fluoro- on the phenyl ring, the instant compound has a 4-chloro, that is :



Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art in possession of the exemplified species with the well enabled variation of compound (which structures have been delineated in CA 128) by the reference would be motivated to prepare the instantly claimed compound 184 because one would expect all the generic taught (see col. 5, lines 15-46) compounds having similar activity. In absence of unexpected results, there is nothing unobvious in choosing the alternative Markush element chlorine in an exemplified compound having fluorine.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mallee et al. CA 137:304712 in view of Rudolf et al. US 6,344,449.

Determination of the scope and content of the prior art (MPEP §2141.01)

Mallee et al. disclosed CGRP antagonistic compounds which are structurally similar, see RN 204695-47-6 or 472966-25-9.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instantly claimed compounds and the prior art compounds is the substituents on the phenyl ring. Rudolf et al. '449 generically described with a well diversified examples that variations of substituents among halogen, methyl, trifluoromethyl, hydroxyl and amino on various positions on the phenyl ring is an optionally choice for one skilled in the art (see examples structure delineated by CA 128).

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art in possession of the Mallee and the Rudolf references would be motivated to prepare the instantly claimed compounds because the modification of one proven compounds with attributes of another proven compound is prima facie obvious.

8. Claims 1-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of US 6,344,449 in view of CA 128:257695.

Claims 1-2 of US 6,344,449 are drawn to two species of compounds which based on the generic teaching of the specification and the exemplified variation as delineated structurally by CA 128 rendered the instant claims prima facie

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One having ordinary skill in the art in possession of the exemplified species with the well enabled variation of compound (which structures have been delineated in CA 128) by the reference would be motivated to prepare the instantly claimed compounds because one would expect all the generic taught (see col. 5, lines 15-46) compounds having similar activity. In absence of unexpected results, there is nothing unobvious in choosing some among many. In re Lemin 141 USPQ 814.

9. Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-19 of copending Application No.

10/835,495 in view of CA 128:257695.

Claims 15-19 of copending SN 10/835,495 are drawn to narrower variation among the Markush elements of the instant claims. Based on the generic teaching of the copending specification and the exemplified variation as delineated structurally by CA 128 rendered the instant claims *prima facie*

One having ordinary skill in the art in possession of the exemplified species with the well enabled variation of compound (which structures have been delineated in CA 128) by the reference would be motivated to prepare the instantly claimed compounds because one would expect all the generic taught (see col. 5, lines 15-46) compounds having similar activity. In absence of unexpected results, there is nothing unobvious in choosing some among many. In re Lemin 141 USPQ 814.

This is a provisional obviousness-type double patenting rejection.

10. The rejection of claims 1-11 under judicially created doctrine of obviousness type double patenting of record will now be applicable to claim 12 and modified as following:

Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over :

1) Claims 1-14 of copending SN 10/683,921 in view of US 6,344,449;

Claims 1-14 are limited to the instant claims wherein W is H, thus are fully embraced by the instant claims.

2) Claims 1-14 of copending SN 10/755,593 in view of US 6,344,449;

Claims 1-14 are drawn to the narrow scope wherein R4 of the instant claims are azacycles with CH₂COOR₂ substitution i.e. the moieties of Rudolf '449, col. 124, C62-C63 while the instant claims are drawn to the alternative moieties of Rudolf '449 of col. 121 C30.

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The difference between the instant claims and copending claims is the prima facie obvious picking and choosing some variations among the many disclosed by Rudolf '449.

3) Claims 1-7 of copending SN 11/107,052 in view of US 6,344,449;

Claims 1-7 are drawn to more limited scope than the instant claims wherein the phenyl rings must be substituted with three substituents which has been exemplified by Rudolf being prima facie obvious variation being two or three substituents at various positions.

4) Claims 1-6 of copending SN 107,195 in view of US 6,344,449;

Claims 1-6 are drawn to more limited scope than the instant claims wherein the R1 moiety is limited to quinazolinone and benzodiazepinone. Rudolf et al. '449 have exemplified that the instant broader Markush alternatives for R1 are prima facie structurally obvious over the two limited species. In absence of unexpected result there is nothing unobvious in choosing some among many. *In re Lemin* 141 USPQ 814.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Applicants' attention is drawn to that the doctrine of obviousness type double patenting is not limited to improper extension but also to prevent possible harassment by multiple assignees. Therefore, even if the copending cases are filed later, if the claimed scope cannot be demarcated clearly to be non-obvious of each other, a terminal disclaimer is required to keep the patents commonly owned.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).


11. Applicants amendment necessitated the new grounds of rejections. No claims allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Feb. 22, 2007


Celia Chang
Primary Examiner
Art Unit 1625